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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,554	06/26/2003	Robert M. Brustowicz	CHD-006	5300
7590 06/12/2009				
David Prashker DAVID PRASHKER, P.C. P.O. Box 5387 Magnolia, MA 01930				
EXAMINER				
PRICE, NATHAN R				
ART UNIT		PAPER NUMBER		
3763				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/606,554

Applicant(s)

BRUSTOWICZ, ROBERT M.

Examiner

NATHAN R. PRICE

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6, 9 and 10 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 6, 9 and 10 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to because the structures depicted in the drawings are difficult to discern. The hand-drawn nature of the drawings combined with the use of shading and cross hatching (for example, in element 80 in fig. 1, and the unlabeled element with a line directed to it towards the rear of the apparatus in fig. 4, among many other elements depicted in the figures) and some graininess present in the drawings, limit the ability of one viewing the drawings to perceive the individual elements depicted and described and the relationships between the elements, even in light of the description in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required

corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to because there is an element in fig. 4, darkly shaded and located toward the rear of the apparatus depicted, which is indicated by a line which seems to be missing a reference number. Applicant should check all drawings to ensure all elements are properly labeled in view of the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 9 is objected to because of the following informalities: "withdrawl" appears twice in the claim and should be spelled "withdrawal"; in part (a), "and radial rotation movement" seems to be grammatically incorrect, and should be amended to either "and radial rotational movement" or "and radial rotation"; in part (b), "said tab engagement" should be "said tab-engagement" to maintain proper antecedent basis. Appropriate correction is required.
4. Claim 10 is objected to because of the following informalities: it is unclear whether non-rotable is a misspelling. If it is intended to mean non-rotatable, the spelling should be corrected. Rotable is a word with a meaning unrelated to the act of rotation. Appropriate correction is required.
5. Applicant should check claims for any other spelling/grammatical errors or errors with antecedent basis which may be present.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 6, 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. Claims 6, 9, and 10 are replete with indefinite descriptive language modifying the elements claimed, including "**configured**" and "**sized**" (any structural element would inherently be configured and sized for its intended function; this language is indefinite

because it is unclear how applicant intends the claimed elements to be "configured" and "sized"), **"of set/fixed dimensions and configuration"** (it is inherent that an elements dimensions or configuration will be fixed in some way; this language is indefinite because it is unclear how applicant intends the claimed elements to be "set" or "fixed" in their configurations), **"discrete"** (as best understood, "discrete" seems to be intended as separate from or standing alone, but since there is no indication from which elements the claimed elements modified by "discrete" are discrete, this language is indefinite), **"at an aligned position"** (indefinite because the claims fail to point out to what the claimed element is aligned); **"at will"** (movement "at will" implies that the element is capable not only of moving itself, but of determining when to move itself; even if one were to assume that this language refers to the will of a user, it is unclear what the language means because an element adapted for rotation would have to be rotatable "at will"); **"on-demand"** (it appears that "on-demand" is intended to limit the type of engagement claimed in some way, but the language is indefinite because it is impossible to determine what is meant by engaging "on-demand"; similar to "at will," "on-demand" implies some desire or will on the part of either the apparatus or the user, but the source of this "demand" and how it relates to the structure of the apparatus is indefinite). This indefinite language appears to be intended to limit the claimed invention in some way, but fails to do so.

9. Many of the terms cited above, such as "aligned", "set", "sized", "fixed", "discrete", and "configured", by the very nature of the terms used, require further description in order to hold meaning and limit the invention. For instance, when an

element is aligned, it must be aligned *in relation to* something, be it an element or a point in space, for the term "aligned" to hold any meaning. It is recommended to either add appropriate language to clarify how this language is intended to limit the claims, or remove this language from the claims.

10. Limitations such as "at will" and "on-demand" also require some clarification as to who or what is exerting its will, and how the apparatus is configured to accommodate the desired operation. In any apparatus configured for operation in some way, it is understood that an operator or controller with a desire or programming to operate the device could operate it. These limitations, therefore, carry no weight. It is recommended to remove this language from the claims, and, if necessary, replace it with language that appropriately reflects the desired functional or structural limitations Applicant intended to claim by including this language.

11. For the purposes of examination, the language discussed above is interpreted as non-limiting.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 6, 9, and 10, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Vaillancourt (US 5591138). Vaillancourt discloses the improvement of an on-demand needle retaining and locking mechanism to prevent

premature withdrawal of the piercing needle into a safety chamber (fig. 1-6), said mechanism comprising: a needle-safety container (hollow collar segment 17, fig. 1) which can be rotated radially on-demand, and has a sized solid tab member 21 (fig. 1) disposed at and extending radially from the open first end at an aligned position (element 21 extends radially, see fig. 1-6, and is disposed at a position aligned with the open first end); and a needle housing 11 (fig. 1) mounted over said needle-safety container (see fig. 1) which is adapted for slidable axial movement (between positions in fig. 1-3) and radial rotation movement (to move element 21 in and out of locking engagement, see fig. 1-3) at will over said needle-safety container, has a hollow spool section (exterior portion of housing 11, fig. 1-6) positioned at and joined to the front end of said needle housing for on-demand engagement with said solid tab member of said needle-safety container after said needle-safety container has been radially rotated (engagement provided by portion 25 of slot 22, fig. 1-6), said hollow spool section comprising a central cavity (area between outer and inner parts of housing 11, fig. 6), open front and rear ends adapted for passage therethrough by a piercing needle (see fig. 6), a tab-engagement segment (elements of slot 22, fig. 1-6), and a pair of sized notches (25 and 23, fig. 1-6) within said tab engagement segment, wherein said spool section is alignable at will with said solid tab member of said needle safety container (see fig. 1-6), said spool section can be engaged by and disengaged from said solid tab member of said rotatable needle-safety container on-demand as a consequence of radially rotating said needle-safety container (as shown in fig. 1-6 in various stages of engagement and disengagement), and the engagement of said spool section with said

solid tab member of said radially rotated needle-safety container provides an on-demand needle retaining and locking mechanism which prevents premature withdrawal of a piercing needle into a safety chamber (see fig. 1-6); a non-rotatable linear segment 20 (fig. 6) which is in an aligned and axial orientation, and a hollow collar segment 17 (fig. 6) which is attached to and aligned with the open front end of said non-rotatable linear segment of said needle-safety container, and can be radially rotated at will independently from said non-rotatable linear segment of said needle-safety container, presents at least one discrete wall of preset dimensions and configuration (see fig. 1-6) and a central void space (interior visible in fig.6), has open front and rear ends adapted for passage therethrough of the tip of a piercing needle (rear and front ends of the wall of 17 are open, see fig. 6).

Response to Arguments

14. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

15. Examiner understands that Vaillancourt has been cited in a previous action, and that Applicant has submitted prior arguments regarding the Vaillancourt reference. Since Examiner has once again applied the Vaillancourt reference, a brief response to those arguments is presented below.

16. Applicant argues that the Vaillancourt reference explicitly requires elements that the present invention does not demand. Examiner maintains that all the elements and functions actually claimed in the instant application (giving the claims their broadest reasonable interpretation) are disclosed in the Vaillancourt reference, as demonstrated

in the rejection above. The additional working parts to which Applicant refers in Vaillancourt are in no way excluded from Applicant's invention as claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN R. PRICE whose telephone number is (571)270-5421. The examiner can normally be reached on Monday-Thursday, 9:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. P./
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art
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